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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,578	02/27/2002	James L. DiGuseppi	9250-29	6023

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bioMerieux, Inc.
Patent Department
100 Rodolphe Street
Durham, NC 27712

EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,578

Applicant(s)

DIGUISEPPI ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 1-9, 11-18, 20 and 21, in the reply filed on July 31, 2006 is acknowledged.
2. Claims 22-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 31, 2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-9, 11, 12, 14-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Bush et al.(US 4,036,698) or Simmons et al.(WO 98/11250) in view of Calandra et al.(US 5,094,955).

The reference of Bush et al. discloses a filtration and detection device that includes a container (11) defining a chamber and having an inlet (13) and an outlet (21) in fluid communication with the chamber. The device includes a filter (26) for filtering fluids and is mounted between the inlet (13) and outlet (21).

The reference of Simmons et al. discloses a filtration and detection device that includes a container (110) defining a chamber and having an inlet (111) and an outlet (112) in fluid communication with the chamber. The device includes a filter for filtering fluids and is mounted between the inlet (111) and outlet (112) (See pages 15-17).

While both of the references of Bush et al. and Simmons et al. disclose adding culture medium to the filter chamber and detecting color or turbidity changes for determining the presence of microorganisms in the sample fluid (See column 5, lines 29-38, of Bush et al. and page 17 of Simmons et al.), claims 1 and 14 differ by reciting that the device includes a sensor

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mounted in the chamber wherein the sensor is positioned at an opposite end of the chamber from the filter.

The reference of Calandra et al. discloses that it is known in the art to mount a growth detection sensor (2) within a sealed culture vessel (1). The reference discloses that using the sensor is advantageous over conventional turbidity and/or color change detections because errors resulting from the presence of interfering materials in the sample can be reduced (See column 2, lines 20-45).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a sensor as taught by the reference of Calandra et al. in the containers of the primary references for the known and expected result of increasing the detecting efficiency within the detection device resulting from the use of the sensor of Calandra et al.

With respect to the location of the sensor, the reference of Calandra discloses that the sensor can be positioned on the bottom of the container or in the sealing means of the container (See column 3, lines 61-68).

As a result, it would have been obvious to one of ordinary skill in the art to determine the optimum location for the sensor within the container while ensuring that the sensor is visible from outside the container. Note, in an already known device, the rearrangement or placement of parts that does not alter the operation of the device is not a patentable distinction (See *In re Kuhle*, 526 F.2d 553, 188 USPQ7 (CCPA 1975)).

With respect to claims 2 and 14, the filter is a microporous filter.

With respect to claims 3 and 15, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum filter configuration while maintaining the required microorganism removal from the sample fluid flowed through the device.

With respect to claims 4-8 and 16, the disclosed use of the sensor of the reference of Calandra et al. meet the limitations recited in claims 4-8 and 16.

With respect to claims 9 and 14, the containers in the references of Bush et al., Simmons et al. and Calandra et al. are transparent.

With respect to claims 11 and 12, while not specifically disclosed by the references of Bush et al. or Simmons et al., it would have been obvious to one of ordinary skill in the art to provide the container with a removable cap and o-ring for the known and expected result of providing access to the interior of the container for removing the filter, if desired, while maintaining an air-tight seal.

With respect to claim 17, in the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of one of ordinary skill in the art to determine the optimum volume of container to employ while maintaining the efficiency of the filtering and detection system.

With respect to claim 18, the containers are made of plastic (See column 3, lines 20-25, of Bush et al.).

With respect to claim 21, the reference of Calandra et al. discloses the use of a measuring apparatus (5) to detect the measurable property of the sensor (2).

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7. Claims 11-13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Bush et al.(US 4,036,698) or Simmons et al.(WO 98/11250) in view of Calandra et al.(US 5,094,955) taken further in view of Greene et al.(US 4,643,197).

The combination of the references of Bush et al. or Simmons et al. with Calandra et al. has been discussed above.

Claims 11-13 and 20 differ by reciting that the inlet and outlet of the device are formed in the lid of the device.

The reference of Greene et al. discloses that it is known in the art to provide both the inlet 38) and outlet (30) of a filter device within the lid structure (26) (See Figure 1).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ a filter device as suggested by the reference of Greene et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, filter a liquid stream while maintaining the removed particles within the container device holding the filter.


Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Beisner
Primary Examiner
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WHB